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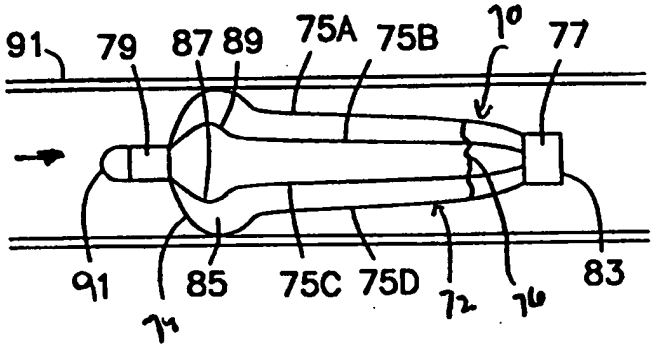
(54) Title: VESSEL OCCLUSION DEVICE

(57) Abstract

The present invention relates to a device for occluding vessels or ducts in a living being. The device includes a main body that has a conical shaped portion terminating in a marker tip. The main body is comprised of an expandable material. The device also includes an anchoring mechanism for anchoring and stabilizing the main body once the main body is positioned in the vessel or duct.



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VESSEL OCCLUSION DEVICE

The present application is a Continuation-In-Part of Provisional U.S. Application No. 60/057,939, filed September 5, 1997.

Background of Invention

The present invention relates to a vessel occlusion device and to a method for occluding a blood vessel or other duct in a living being.

Endovascular therapy has been used to treat conditions such as internal bleeding, tumor growth, and vessel wall pressure in a region of aneurysm. In particular, endovascular therapy has included a step of occluding blood supply to tumors and relieving vessel wall pressure in a region of vessel aneurysm. Endovascular therapy has included mechanically based therapy as well as chemically based therapy. Catheters have played a significant role in performing endovascular therapy.

One challenge in successful endovascular therapy is that a target site which requires treatment may be in a region of an organism, such as the brain, which requires catheter placement along a tortuous path that includes small vessels or ducts, such as arterial vessels.

One method for performing therapeutic embolization procedures, such as is described in the Gianturco patent, U.S. No. 5,334,210, issuing August 2, 1994, employs a detachable, inflatable balloon formed of a material such as latex or silicone. During an embolization procedure, the detachable balloon is attached to a distal end of a delivery catheter and positioned at a treatment site using a visualization aide such as fluoroscopy. Once positioned, the balloon is filled with a solidifying gelatinous fluid or contrast media. Secure anchoring is then tested. If necessary, the balloon is additionally then filled and mechanically detached from the delivery catheter. The gelatinous fluid solidifies and the balloon occludes the blood vessel at the treatment site.

The second type of mechanical vaso-occlusive device is a wire coil which can be introduced through a catheter in a stretched linear form and which assumes a helical wire shape when released into a vessel. The wire itself tends

to be relatively stiff and shape retaining and typically made of platinum or stainless steel in a coil shape. The wire is sometimes coated with filaments such as Dacron® or cotton fibers which provide a substrate for clot formation in an interior region of a vessel while the coil serves to anchor the device on the vessel wall at a site of release.

U.S. Patent No. 5,639,277 issuing June 17, 1997, describes a surgical device for forming a vessel occlusion or embolism. The device is a helically wound coil in which a helix is wound in such a way as to have multiple axially offset longitudinal or focal axes. The device also includes small diameter secondary coil windings that are adjacent large diameter coil windings. The device is sufficiently flexible and small that it may be delivered to a site within vessels or ducts of the human body using a pusher and a catheter.

The Neuss Patent, U.S. No. 5,536,274, issuing July 16, 1996, describes a spiral implant for blood vessels. The implant is advanced to a desired site in a living being by advancement of a catheter in which the implant is positioned. The implant is displaced from the catheter by displacement of an insertion wire upon which the implant is positioned. The implant is displaced in an extended shape to the intended site for location. The implant is formed into a secondary shape by withdrawing the guidewire or by pushing forward a stripping element. Once the implant is in a desired position, the implant is stripped off the guidewire using the stripping element.

U.S. Patent No. 4,994,069, issuing February 19, 1991 describes a vessel-occlusion coil wire device. The device has a relaxed condition in which the wire assumes a folded, convoluted conformation, a stretched condition. The wire also has a stretched condition so that the wire can be pushed through a catheter. The wire additionally has a memory which returns the wire from its stretched condition to its relaxed condition. When the wire is released from the catheter, the wire forms a vaso-occlusive body.

Description of the Drawings

Figure 1 illustrates a linear cross-section view of one embodiment of the vessel occlusion device of the present invention.

Figure 2 illustrates a linear cross-section view of one other embodiment of the vessel occlusion device of the present invention in cross-section.

Figure 3 illustrates the embodiment of Figure 2 in radial cross-section.

Figure 4 illustrates another embodiment of the vessel occlusion device in linear cross-section with an attachment device attached to the occlusion device.

Figure 5 illustrates the embodiment of Figure 4 in radial cross-section.

Figure 6 illustrates a side-sectional view of one other embodiment of the device of the present invention.

Figure 7 illustrates a cross-sectional view of the embodiment of Figure 6.

Figure 8 illustrates a side view of the device of claim 6 where the device of Figure 6 contacts a vessel wall.

Figure 9 illustrates one additional embodiment, inside view, of the device of the present invention.

Summary of the Invention

The present invention includes a device for occluding vessels or ducts in a living being. The device includes a main body with a conical shaped portion terminating in a marker tip. The main body is comprised of an expandable material. The device may also include an anchoring mechanism for anchoring and stabilizing the main body once the main body is positioned in a vessel or duct and may include a positioning mechanism for adjusting the position of the device at a site of occlusion.

The present invention also includes a method for occluding vessels or ducts in a living being. The method includes providing a device comprising a main body with a conical-shaped portion terminating in a marker tip. The main body is comprised of an expandable material. The device also includes an anchoring mechanism for anchoring and stabilizing the main body once the main body is positioned in a vessel or duct. The method also includes a step of transporting the device to a site of occlusion. The device is transported in a compressed position. Once at the site of occlusion, the device is expanded and anchors itself in the vessel or duct.

Detailed Description of Preferred Embodiments

The occlusion device of the present invention illustrated in one embodiment generally at 10 in Fig. 1 includes a cylindrical main body 12 having a distal end 21 and a conical-shaped portion 14 integral with the main body 12 that terminates in a distal end 16 of the occluding device 10.

The cylindrical main body 12 with the conical-shaped portion 14 is defined and stiffened by a wire frame 15 made of a material such as wire or braid. The conical-shaped portion 14 is part of the frame 15 and is also made of wire or braid. The wire or braid renders the device 10 flexible. For instance, the device 10 is expandable from a first collapsed position once the device 10 is inserted into a blood vessel and is positioned at a site where occlusion is desired such as is shown in Figure 1. In one embodiment, the device 10 has a compressed cross-section diameter of about 0.020 inches and an expanded diameter of about 4.0 millimeters. Most preferably, the braid or wire is self-expanding so that the device naturally expands from a first compressed position to a second expanded position at the site of occlusion in order to release a natural tension from the compression or in response to a memory imparted to the wire or braid. While in the collapsed position, the device 10 is transported to a site of occlusion in a second catheter. The device 10 naturally expands once released from the catheter.

The wire or braid used in the device 10 is a filament having a diameter of about 0.005 inches and most preferably about 0.003 inches. The wire may be flat, square, round, half-round or triangular in cross-section. The filament or wire may be made from such biocompatible metals, polymers, or alloys, as platinum, palladium, rhodium, gold, silver, tungsten, iridium, nickel-titanium alloys, Elgiloy, various stainless steels as well as materials coated with a biocompatible coating. Alloys such as platinum and tungsten are also suitable. Suitable biocompatible polymers for use as wire or filament include polyethylene, polyurethane, polyester, and polypropylene. It is also believed that polymers such as nylon, Teflon®, and inorganic materials such as fibrous carbon are also suitable for use in the present invention.

The wire or filament is most preferably woven to make a cross-hatch pattern or a mesh pattern. It is important that wires or fibers in the pattern have a capacity to slidably move over each other in order to render the device 10 having the first collapsed position and second expanded position. In one embodiment, wire or filament is woven at about 40 to 120 pics per inch. It is also important that the wire have sufficient rigidity and strength to resist deformation when inserted in a vessel such as a blood vessel.

The device 10 terminates at the distal end 16 in a tip marker 18. The tip marker 18 is most preferably made of a radiopaque material, such as gold, tungsten, tantalum or the like. Alternatively, the tip marker 18 may be coated with a radiopaque material. The marker 18 has a diameter of about 0.016 inches.

The device 10 of the present invention is a significant improvement over a use of inflatable detachable balloons as occlusion devices. The balloons have a tendency to slowly deflate, thereby causing migration from the desired site of occlusion. The self-expanding device 10 does not deflate with use.

The device 10 is self-expanding an is also self-anchoring within a vessel or duct. The device 10 anchors itself by expanding to a diameter that blocks the vessel or duct. The self-expanding occlusion device 10 of the present invention requires no additional components or devices or fluid to position itself at the desired site.

It may be desirable during occlusion to promote a rapid thrombosis. It is contemplated that the device of the present invention at 10 could be made of thrombogenic material or coated with thrombogenic materials in order to accelerate thrombosis.

One other embodiment of the vessel occlusion device of the present invention is illustrated at 30 in Fig. 2. The device 30, the "umbrella" device, includes a plurality of self-expanding, stiffening ribs 32 (a-d) and a polymeric sheath or covering 34 attached to the ribs. The covering 34 illustrated in Fig. 2 substantially covers the ribs 32 (a-d). In an embodiment such as is illustrated at 76 in Fig. 6, the covering partially covers an array of struts 75 (a-d) while leaving a portion of each strut, as shown at 70, uncovered. A radial cross-sectional view of the device 30 is illustrated in Fig. 3. The ribs 32 (a-d) terminate at a distal end

36 of the device by attachment to a radiopaque marker 38. The ribs 32 (a-d) may range from a number as low as 4 or as high as desired. The ribs 32 (a-d) are preferably made of a spring stainless steel or a super elastic Nitinol or a shape memory Nitinol. The ribs 32 (a-d) are preferably permanently adhered by a technique such as soldering or brazing, to the marking tip 38. The polymeric sheath may be adhered to the ribs with an adhesive or may be self-adhered due to intrinsic adhesive characteristics on each of the ribs or the sheath. The umbrella occlusion device 30 is also conveyed to a desired vessel or duct site by a second catheter. The device 30 is conveyed in a collapsed state. Once the device 30 is released at the desired vessel or duct site, the device 30 self-expands due to a memory imparted into the rib material. As the ribs 32 (a-d) expand, the polymeric sheath 34 is placed under tension. The device 30 may be transferred from the catheter to the site by a pushing tool.

A land length 40 is designed for the device 10 or 30 so that as the device 10 or 30 is deployed, the device contacts a vessel or duct wall and anchors prior to the device fully exiting the delivery catheter. The land length 40 range is distance equal to or greater than the diameter of the vessel into which the device is to be implanted. Land length as used herein refers to the length of the annular, non-conical portion of the main body of the device 10. The length of ribs or the self-expanding land length such as is illustrated at 11 in Fig. 1 ensures centering of the device in a vessel or duct.

One other embodiment of the umbrella device is illustrated at 50 in Fig. 4. The device 50 also includes a plurality of ribs 52 (a-d) and a polymeric sheath 54 attached to the ribs 52 (a-d). A radial cross-sectional view of the device in Fig. 4 is illustrated at 50 in Fig. 5.

The umbrella type devices 10, 30, and 50 may be molded as a single unitary main body. The molded material would be a polymeric material that imparts a sufficient strength and stiffness in order to maintain the shape such as is shown in Figures 2 and 4. In this embodiment, the ribs have a greater thickness than the sheath.

One additional embodiment of the device of the present invention is illustrated generally at 70 in Figure 6. Device 70 includes a main body 72 with a

skeletal component 74 and a sheath component 76 supported by and covering the skeletal component 74. The skeletal component includes an array of struts 75 (a-d) attached at each of the distal end 77 and proximal end 79 of the device 70 at a radiopaque marker 81 or 83. The struts 75 (a-d) are made of a material such as Nitinol, stainless steel or Elgiloy. The covering 85 may be any flexible, biocompatible polymer.

The struts 75 (a-d) are asymmetric with respect to the proximal end and distal end 77 and 79. In particular, adjacent to the proximal end 79, the struts extend outwardly like an umbrella forming an annular protrusion 87. The annular protrusion 87 abuts a wall 89 of a blood vessel 90. The abutment increases forces against the wall 89 for improved vessel sealing. The nature of sealing of the device in Figure 6 is a point of contact type sealing. An attachment loop 91 may also be used to facilitate delivery of the device to a desired point of contact.

The device 70 encloses a hollow region. It is contemplated that the hollow region 86 may be filled with a drug in liquid or gel form. The hollow region 86 is shown in cross-section in Figure 7.

The device 70 provides an improved opacification with dual markers and improved sealing and self-centering characteristics as compared to conventional devices. One other embodiment of the device of the present invention is illustrated at 100 in Figure 9. The device 100 includes an array of spiral struts 102 (a-d) that terminate at each of a distal end 104 and proximal end 106 at respective radiopaque markers 108 and 110. The struts 102 (a-d) are covered by a polymer 112. The polymer 112 is flexible and biocompatible. The polymer 112 is also attached to one of the markers 108 and 110. The spiral struts 102 (a-d) improve the sealing characteristics of the device 100 to the vessel wall thereby reducing any risk of leakage between the polymer covering 112 and the vessel wall.

The device of the present invention 10, 30, 50, 70 or 100, is preferably delivered to a desired site through the use of a second catheter. The second catheter preferably includes an end hole through which the device may be transferred. The transfer occurs with the use of a pushing tool. In one

embodiment, the second catheter has a pushing tool passing through its access. The pushing tool includes a sheath attachable to an axial end of the device 10 of the present invention. The device 10 is releasable upon pushing the axially placed pushing tool against the proximal end 20 of the occlusion device 10 and the device 10 is pushed through the sheath.

In deployment of any of the embodiments of the occlusion device of the present invention, the device is positioned so as to be antigrade to flow, that is, the proximal end of each of the device embodiments faces the flow. Deploying the device in this manner allows for the self-expanding ribs 32 (a-d) and anchor hooks such as are illustrated at 56 a-d in Fig. 4 to deploy first. The anchor hooks 56 a-d anchor the device to the wall of a vessel or duct. By releasing the anchor hooks 56 a-d first, improved positioning or any possible necessary repositioning is achievable. The anchor hooks 56 a-d have a length of about 0.005 inches.

To ensure proper positioning of the main body in the devices 10, 30, or 50, 70 or 100, the device includes a mechanism to reconstrain the device in the delivery catheter prior to repositioning. Repositioning is performed by use of an attachment mechanism, attachable to the occluder such as is illustrated at 58 in Fig. 2 and 60 in Fig. 4. The attachment mechanism 58 or 60 may be attachable to the pushing tool mechanism by an electromechanical link, a fusible joint, or a threaded male or female joint. Preferably, the attachment mechanism is attachable to a loop 62 on the marker point 59 of the device 50. The attachment mechanism 58 or 60 includes one or more gripper elements 64 or 66 that are reversibly insertable throughout the loop 62. The gripper elements, once inserted through the loop may grab the device and reposition or optimize the position of the device within a vessel or a duct.

The aforementioned description is not to be interpreted to exclude other occlusion devices advantageously employing the present invention. Other embodiments may be desired by those skilled in the art without departing from the spirt and scope of the present invention.

IN THE CLAIMS

What is claimed is:

1. A device for occluding vessels or ducts in a living being, comprising:

a main body that includes a conical-shaped portion terminating in a marker tip, the main body comprised of an expandable material; and

anchoring means for anchoring and stabilizing the main body once the main body is positioned in the vessel or duct.

2. The device of claim 1 wherein the main body is comprised of self expandable material.

3. The device of claim 1 wherein the main body includes an annular portion having a length, L, effective for anchoring the device, and the conical-shaped portion, integral to the annular portion.

4. The device of claim 3 wherein the annular portion is effective for self centering the device.

5. The device of claim 3 wherein the annular portion length is effective for self-positioning and stabilizing the device in the vessel or duct.

6. The device of claim 1 wherein the main body is formed from a filamentous material.

7. The device of claim 1 wherein the main body and conical-shaped portion are defined by a plurality of expandable ribs.

8. The device of claim 1 wherein the main body is defined by a plurality of ribs overlaid with a polymeric sheath attached to the ribs.

9. The device of claim 1 wherein the conical-shaped portion has a "umbrella" shape.

10. The device of claim 1 and further including an eye loop on the marker tip.

11. The device of claim 1 wherein the anchoring means comprises a foot segment substantially parallel to a radial cross section of the main body.

12. A method for occluding vessels or ducts in a living being, comprising:

providing a device that comprises a main body with a conical-shaped portion terminating in a marker tip, the main body comprised of an expandable material and an anchoring means for anchoring and stabilizing the main body once the main body is positioned in the vessel or duct;

transferring the device to a site of occlusion wherein the device is in a compressed state;

expanding the device at the site of occlusion; and

anchoring the device at the site of occlusion.

13. The method of claim 12 wherein the device includes a loop positioned on the marker tip.

14. The method of claim 12 and further including repositioning the device at the site of occlusion.

15. The method of claim 1 wherein the main body is overlaid with a polymeric sheath.

16. The method of claim 1 wherein the main body is made by an injection molding step.

17. The device of claim 1 wherein the main body encloses a space.

18. The device of claim 1 wherein the main body is defined by an array of struts, the struts defining a protrusion for contacting a wall of the vessel or duct.

19. A device for occluding vessels or ducts in a living being, comprising:

a main body that includes a conical-shaped portion terminating in a marker tip, the main body comprised of a self expandable material; and

anchoring means for anchoring and stabilizing the main body once the main body is positioned in the vessel or duct, the main body including an annular portion having a length, L, effective for anchoring and self-centering the device, and the conical-shaped portion, integral to the annular portion.

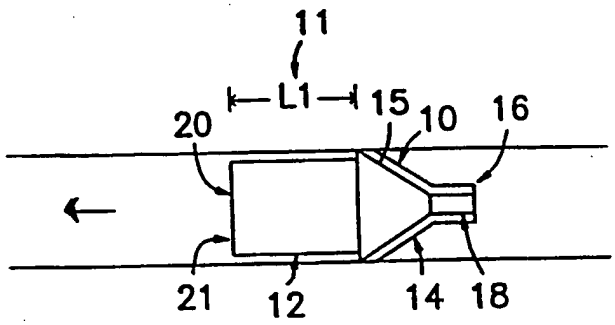

FIG. 1

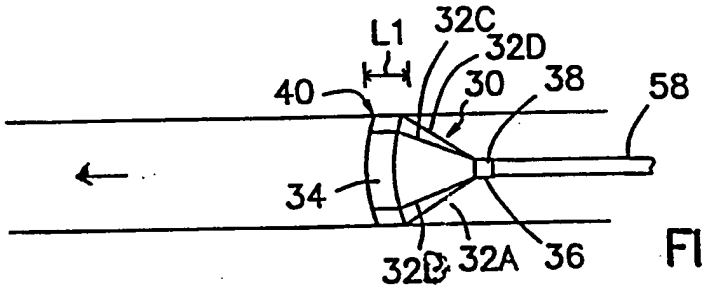

FIG. 2

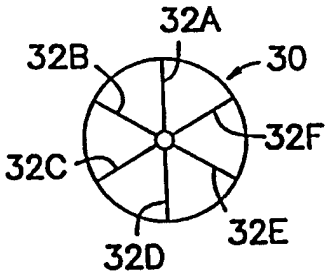

FIG. 3

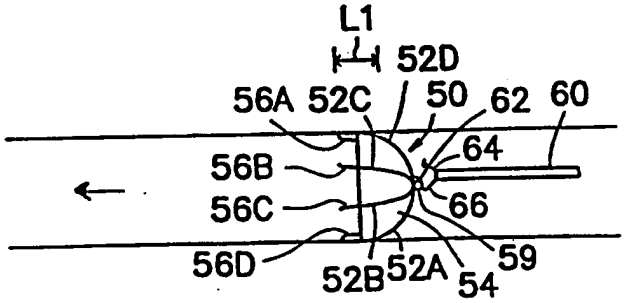

FIG. 4

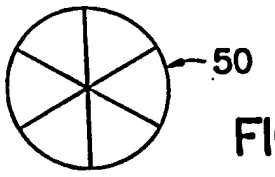

FIG. 5

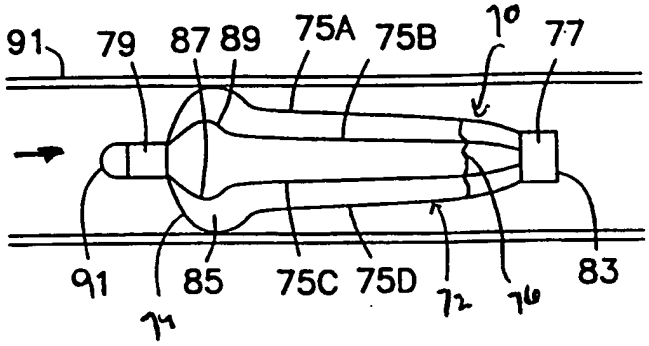

FIG. 6

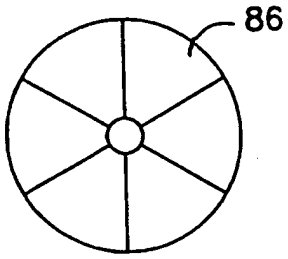

FIG. 7

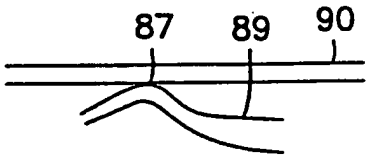

FIG. 8

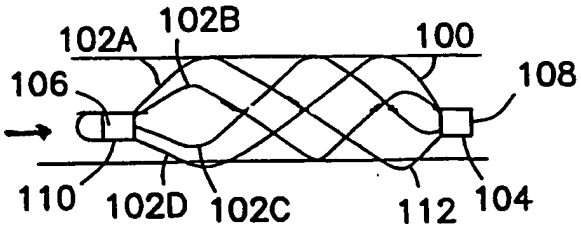

FIG. 9

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 98/18014

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/12

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 31672 A (B. BRAUN MEDICAL, INC.) 4 September 1997 see the whole document	1-6,17, 19
Y	---	7-11,18
Y	US 4 710 192 A (LIOTTA ET AL.) 1 December 1987 see the whole document	7-9,11, 18
Y	---	10
	DD 233 303 A (HUMBOLDT-UNIVERSITAET ZU BERLIN) 26 February 1986 see abstract; claims 1,6,15; figures see page 3, line 57-67	

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 October 1998	04/11/1998

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inte :onal Application No
PCT/US 98/18014

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 27893 A (TRANSVASCULAR, INC.) 7 August 1997 see abstract; figures 4-18 see page 5, line 20-24 see page 15, line 1 - page 16, line 35 see page 24, line 23-34	1-9, 17-19
A	DE 92 05 797 U (SCHMITZ-RODE) 17 June 1992 see page 3, line 1-31; figures	1-8,11, 17-19
A	US 5 656 036 A (PALMAZ) 12 August 1997 see abstract; figures see column 3, line 61 - column 4, line 29	1-8,17, 19

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/18014

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12-16
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 98/18014

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